Nominal size in six bileaflet mechanical aortic valves: A comparison of orifice size and biologic equivalence

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Objectives: Nominal size remains the standard by which valves are compared, but its relationship with orifice area and the patient tissue annulus diameter may differ according to valve design. The aims of this study were to measure the orifice size and compare biologic equivalence in six bileaflet mechanical heart valve designs.

Methods: The inflow aspect of each of 29 valves was photographed then digitized, and the maximum internal diameter and orifice area were calculated. Biologic equivalence was assessed with a series of machined polypropylene blocks.

Results: The orifice area ranged between 159 and 222 mm^2 for the six size 19 valves. The internal diameter ranged from 1.6 to 4.6 mm less than the manufacturer's nominal size. Biologic equivalence assessed from an estimate of tissue annulus diameter with machined blocks ranged from 1.0 and 3.5 mm larger than nominal size for the intra-annular valves. This diameter ranged from 3.5 mm smaller to 1.5 mm larger than nominal size for the supra-annular valves.

Conclusion: There are major differences between nominal size and biologic equivalence. This may lead to confusion when attempting to make comparisons between different valve designs with the same nominal size. A clearer sizing nomenclature is required and could be based on in vitro assessment of tissue annulus diameter or an alphanumeric code.

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A bileaflet mechanical valve is described by a nominal size, which is broadly consistent with the diameter of the patient tissue annulus it is intended to fit. This is also true of most other designs of replacement valve, save for the Starr-Edwards caged-ball prosthesis. Thus literature reviews[1,2] and studies of hemodynamic function[3-6] commonly compare valves by nominal size. The assumption is that, irrespective of manufacturer or model, all valves of a certain nominal size are interchangeable for a given patient tissue annulus diameter.

This assumption leads to nominal size being substituted for the measured left ventricular outflow tract diameter during the calculation of the continuity equation[7]. Some studies suggest that this may be valid,[8] whereas others do not.[9] Similarly, echocardiography is often used for estimating the size of the substitute valve either before surgery or perioperatively,[10-13] although differences between nominal valve size and left ventricular outflow tract diameter are often large.[11] In fact, nominal size and patient tissue annulus diameter may not agree.[14] In terms of biologic equivalence, it may be more appropriate to compare valves of different nominal diameter for some valves made by different manufacturers. Therefore the aims of this study were to measure the orifices of a number of designs of bileaflet mechanical aortic valve and to compare nominal size with biologic equivalence, as assessed with an artificial patient annulus.

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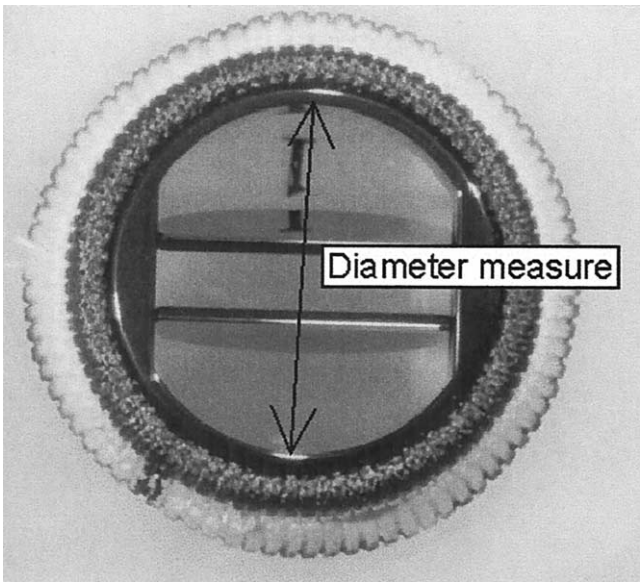

Figure 1. Method of measuring internal diameter. Digitized image of inflow surface of Carbomedics standard valve with internal diameter as used in calibration procedures.

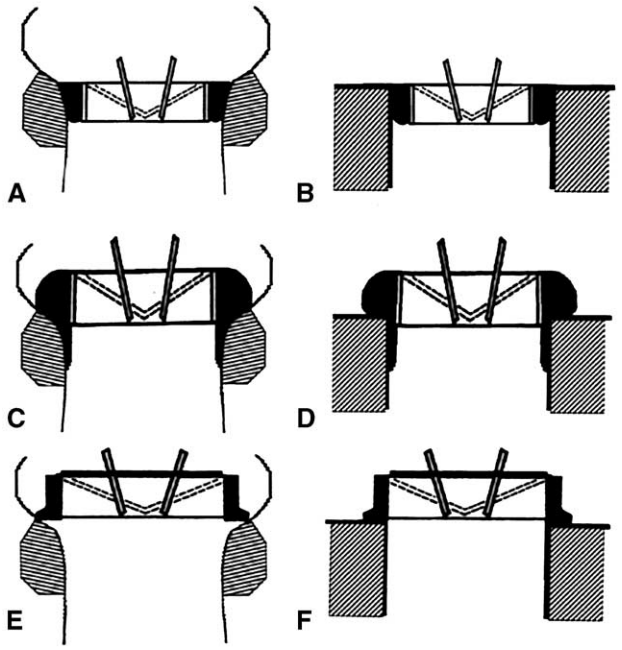

Figure 2. Diagrams of bileaflet mechanical valves. Intra-annular valve (eg, Carbomedics standard or St Jude Medical standard) as implanted in patient (A) and as inserted into annulus machined in polypropylene block (B). Supra-annular valve with component of housing designed to fit within annulus (eg, Medical Carbon Research Institute On-X and St Jude Medical EHP) as implanted in patient (C) and as inserted into annulus machined in polypropylene block (D). Supra-annular valve with no intra-annular component (eg, Carbomedics Top Hat) as implanted in patient (E) and as inserted into annulus machined in polypropylene block (F).

Methods

Valves

In response to requests to several manufacturers, 29 clinical quality valves were donated by Medical Carbon Research Institute (On-X; Medical Carbon Research Institute, LLC, Austin, Tex), St Jude Medical (standard and expanded cuff high performance; St Jude Medical Inc, Minneapolis, Minn), and Sulzer Carbomedics (standard, reduced cuff, and supra-annular; Sulzer Carbomedics Inc, Austin, Tex). Valves sized 19 through 25 for the On-X and 19 through 27 for the other designs were studied.

Photography

The leaflets were held fully open, and the inflow surface was photographed onto 35-mm transparency film (Kodak Ektachrome; Eastman Kodak Company, Rochester, NY) with an Olympus OM-4Ti camera with Olympus SZH Stereomicroscope (7×-40× magnification; Olympus Optical Co, Ltd, Tokyo, Japan). This was aligned with the central axis of the valve. The images were digitized with a Hewlett-Packard Scanjet 4C (Hewlett-Packard Company, Palo Alto, Calif) scanner (Figure 1) then analyzed manually with Adobe Photoshop (Adobe Systems Incorporated, San Jose, Calif). A program was then written in MATLAB (The MathWorks, Inc, Natick, Mass) to allow calibration and elimination of errors caused by variations in image magnification. For each image the maximum internal diameter in pixels was calibrated from the corresponding internal diameter measured directly with a digital caliper (resolution 0.01 mm; Mitutoyo Corporation, Kanagawa, Japan). Measurement errors resulting from manual edge detection and digitization were estimated from image analysis of a series of machined cylinders of known diameter between 19 and 31 mm. Computed areas were within ± 1.5% of the actual area calculated from the known diameter.

Cylindric Fit

Polypropylene cylindric blocks were machined to produce a series of annuli with core diameters ranging between 17 mm and 35 mm in 0.5-mm increments. Each valve with an intra-annular component was tried in a range of blocks until a snug fit was obtained without the need for excessive force. This was appropriate for valves intended for intra-annular implantation (St Jude standard and Carbomedics standard and reduced cuff; Figure 2, *A* and *B*) and for those supra-annular valves in which a portion of the housing is implanted within the annulus (Medical Carbon Research Institute On-X and St Jude expanded cuff high performance [EHP]; Figure 2, *C* and *D*). The Carbomedics supra-annular valve has no intra-annular component (Figure 2, *E*), and the outer edge of the valve orifice was therefore matched to the annulus of the block (Figure 2, *F*). These measurements were termed the *cylindric fit* and were intended as a measure of biologic equivalence.

Analysis

For the pixel-based measurements (internal diameter and internal orifice area), one measurement was taken. The cylindric fit was expressed as the modal value from three observers. All three observers agreed exactly in 11 of 29 cases (38%), and there was at most a 0.5-mm difference for the other 18 (62%).

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TABLE 1. Measurements of inside diameter and geometric orifice area in 29 bileaflet mechanical valves of six different designs arranged by labeled size

Labeled size	Make	Inside diameter (mm)	Inside area (mm^2)
19	CM Std	14.7	159
19	CM R	14.7	160
19	CM TH	14.7	160
19	SJ Std	14.8	163
19	SJ EHP	16.6	208
19	MCRI On-X	17.4	222
21	CM Std	16.7	208
21	CM R	16.7	207
21	CM TH	16.7	208
21	SJ Std	16.6	208
21	SJ EHP	18.6	263
21	MCRI On-X	19.4	280
23	CM Std	18.5	256
23	CM R	18.5	258
23	CM TH	18.5	256
23	SJ Std	18.6	260
23	SJ EHP	20.4	313
23	MCRI On-X	21.4	343
25	CM Std	20.5	316
25	CM R	20.5	314
25	CM TH	20.5	316
25	SJ Std	20.4	315
25	SJ EHP	22.4	385
25	MCRI On-X	23.4	405
27	CM Std	22.5	383
27	CM R	22.6	387
27	CM TH	22.6	384
27	SJ Std	22.5	386
27	SJ EHP	24.2	445

Measurements are to the nearest 1 mm^2 for area and the nearest 0.1 mm for diameter. *CM,* Sulzer Carbomedics; *Std,* standard; *R,* reduced cuff; *TH,* supra-annular Top Hat; *SJ,* St Jude Medical; *MCRI,* Medical Carbon Research Institute.

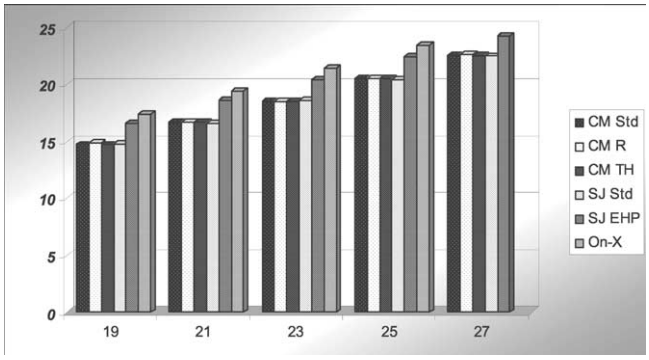

Figure 3. Internal diameter in relation to nominal size for six designs of bileaflet mechanical valve. *CM,* Sulzer Carbomedics; *Std,* standard; *R,* reduced cuff; TH, supra-annular Top Hat.

TABLE 2. Biologic equivalences of different types of valves implanted in the intra-annular position as assessed by cylindric fit

Cylindric fit	Make	Labeled size (mm)	Orifice area (mm^2)
20	CM R	19	160
21	SJ Std	19	163
21.5	CM Std	19	159
22	CM R	21	207
22.5	SJ Std	21	208
23.5	CM Std	21	208
24	CM R	23	258
24.5	SJ Std	23	260
25.5	CM Std	23	256
26	CM R	25	314
27	SJ Std	25	315
27.5	CM Std	25	316
28.5	CM R	27	387
29	SJ Std	27	386
30	CM Std	27	383

CM, Sulzer Carbomedics; *R,* reduced cuff; *SJ,* St Jude Medical; *Std,* standard.

Results

Table 1 shows the measurements for all valve types by nominal size. The inside diameter was larger for the On-X and St Jude EHP valves than for the other valve designs at all nominal sizes tested (Figure 3). Compared with the manufacturer's nominal size, the internal diameter of the orifice was 1.6 mm less for the On-X, 2.4 to 2.6 mm less for the St Jude-EHP, 4.3 to 4.6 mm less for the St Jude standard, and 4.3 to 4.5 mm less for both Carbomedics designs.

Table 2 shows cylindric fits for valves designed for implantation in the intra-annular position. Cylindric fit was between 1 and 1.5 mm larger than nominal size for the Carbomedics reduced cuff, between 1.0 and 2.0 mm larger for the St Jude standard, and between 1.5 and 3.0 mm larger for the Carbomedics standard.

Table 3 shows cylindric fits for valves designed for supra-annular implantation. The cylindric fit was smaller by between 2.0 and 3.5 mm for the Carbomedics supra-annular (Top Hat), smaller by between 0 and 0.5 mm for the St Jude EHP, and larger by between 1.0 and 1.5 mm for the Medical Carbon Research Institute On-X. Thus according to this model, a Carbomedics Top Hat valve was approximately biologically equivalent to a St Jude EHP valve one size smaller and an On-X valve two sizes smaller.

Discussion

This study shows that the nominal size of six frequently-implanted designs of bileaflet mechanical heart valve from three different manufacturers may be seriously misleading if assumed to be identical to the intended patient tissue annulus diameter or to reflect the size of the prosthetic orifice.

TABLE 3. Biologic equivalences of different types of valves implanted in the supra-annular position, as assessed by cylindric fit

Cylindric fit	Make	Labeled size (mm)	Orifice area (mm^2)
17	CM TH	19	160
18	CM TH	21	208
18.5	SJ EHP	19	208
19.5	CM TH	23	256
20	MCRI On-X	19	222
20.5	SJEHP	21	263
21.5	CM TH	25	316
22.5	MCRI On-X	21	280
23	SJ EHP	23	313
24	CM TH	27	384
24.5	MCRI On-X	23	343
25	SJ EHP	25	385
26.5	MCRI On-X	25	405
26.5	SJ EHP	27	445

CM, Sulzer Carbomedics; *TH,* supra-annular Top Hat; *SJ,* St Jude Medical; *MCRI,* Medical Carbon Research Institute.

The measured orifice area ranged between 159 and 222 mm^2 for the six size 19 valves and between 316 and 405 mm^2 for the six size 25 valves (Table 1). This is consistent with previous studies that have noted the disparity between nominal and actual size not only for bileaflet valves but also for tilting-disk mechanical and stented and stentless tissue valves.[14,15] Christakis and colleagues[14] therefore suggested that valves should be labeled by internal diameter. However, valves of the same internal diameter may have sewing cuffs that are very different in size and compressibility. This means that valves of a similar orifice area may not be capable of implantation in a given patient. We therefore compared valves with a measure of biologic equivalence provided by a series of machined polypropylene blocks.

The difference between nominal size and biologic equivalence varied widely. At one extreme, the biologic equivalence was as much as 3.5 mm smaller than nominal size for the Carbomedics supra-annular (Top Hat) valve; at the other, the biologic equivalence was 3.0 mm bigger for the Carbomedics standard valve. For the intra-annular valves, each nominal size of Carbomedics standard valve was approximately equivalent to the Carbomedics reduced cuff of the next nominal size larger. For the supra-annular valves, the Carbomedics supra-annular (Top Hat) was approximately equivalent to a St Jude EHP one size smaller and an On-X valve two sizes smaller. Discrepancies in comparing supra-annular and intra-annular valves were even greater. The Carbomedics standard size 19 valve was biologically equivalent to the Carbomedics supra-annular (Top Hat) size 25 valve, which fitted a similar sized polypropylene block.

It is clear that comparing hemodynamic function in bileaflet mechanical valves of the same nominal size is usually inappropriate. It would be tempting to compare valves with similar geometric orifice areas,[14] for example the 19 St Jude EHP with either the 21 Carbomedics standard, the 21 Carbomedics supra-annular (Top Hat), or the 21 St Jude Medical standard. This might be reasonable in the in vitro setting, but clinically it makes more sense to compare biologically equivalent valves that could be implanted into the same patient tissue annulus. Research studies investigating hemodynamic function should either use the tables of biologic equivalence established here (Tables 2 and 3) or alternatively randomly assign the valve types being compared. An independent sizer could be used to measure the actual diameter of each individual patient's annulus, then the sizers for each of the investigational valve types should be used in turn before opening the randomization envelope. The different valve types should then be compared according to the patient tissue annulus, rather than the nominal size.

The difference between nominal size and biologic equivalence also means that extreme caution should be exercised when attempting to size a valve by echocardiography. Studies attempting this show mostly good agreement between left ventricular outflow tract diameter for stentless valves.[10] However, as much as 2 mm difference was shown in one study[13] of mechanical and stented biologic valves. In another,[11] the 95% range for the difference between left ventricular outflow tract diameter measured by transthoracic echocardiography and nominal valve size was between −8.5 and 5.1 mm. The difference between nominal size and diameter measurement depends on the valve design. The results in this study suggest that for the St Jude EHP valve there would be exact agreement, for the Carbomedics reduced cuff series there would be about 1 mm difference, but for the Carbomedics standard the left ventricular outflow tract diameter could be as much as 3 mm larger than the nominal size.

Similarly, it is usually inappropriate to substitute the nominal size of the replacement heart valve in place of direct measurement of the outflow tract when applying the continuity equation.[7,8] This has been advocated on the basis of better discrimination between valve sizes in St Jude Medical standard valves.[8] In fact, use of the nominal diameter caused a systematic overestimation of effective orifice area by 0.2 cm^2 relative to direct measurement, and individual paired values were as much as 1.0 cm^2 different.[8] That finding is consistent with this study, because we showed that cylindric fit, which is equivalent to left ventricular outflow tract diameter, was larger than nominal size by about 1 to 1.5 mm for St Jude Medical standard valves. A study of stented biologic prostheses[9] showed that the correlation with catheter-derived effective orifice area was

poorer when the continuity equation was calculated with the nominal size than when the measured left ventricular outflow tract diameter was used. However, it is clear that the relationship between nominal size and outflow tract diameter depends on the type of valve and whether the valve is implanted in an intra- or supra-annular position.

Definitions of patient-prosthesis mismatch must also be tightened. It has been suggested[16] that a size19 valve should not be implanted in a patient with a body surface area larger than 1.7 m^2. However the geometric orifice area of a size 19 valve depends on the site of implantation and the valve design and in this study varied by a factor of 1.4 between the largest and smallest bileaflet mechanical valves. Furthermore, the cylindric fit of a size 19 valve ranged from 17 mm to 21.5 mm, depending on position and valve type. Clearly, any guidance regarding prosthesis-patient mismatch must include geometric or preferably effective orifice area, rather than nominal size,[17] and we suggest also a measure of biologic equivalence as provided by cylindrical fit.

Toward a Standardized Nomenclature

It should be possible for the label on the case containing the valve to reflect the true size of that valve. We suggest that the most clinically useful measure would be the tissue annulus diameter, because this should reflect the diameter of the patient's annulus. This could be tested in vitro in terms of biologic equivalence as measured by cylindrical fit (Tables 2 and 3). However, the relationship between the true valve size and the annulus depends on a number of factors, including suture technique and to what degree the surgeon compresses the cuff. There was a variation in biologic equivalence of 0.5 mm among the three observers in this study for 18 of the 29 valves, probably reflecting differences in assessing cuff compressibility. For valves intended for supra-annular implantation, the diameter of the aorta and position of the coronary arteries may also affect the size of valve suitable for implantation. An alternative approach is an alphanumeric code, as for the Starr-Edwards valve, with for example 1A for the smallest aortic valve of any given type. We suggest that whatever sizing convention is used, it would also be useful to have the geometric orifice area displayed on the label of the container, as suggested by Christakis and colleagues.[14]

Limitations

The conditions in this study cannot completely reflect every clinical situation. The native aortic annulus is usually more flexible than the polypropylene cylinders used in this study. This may affect biologic equivalence, particularly for the On-X valve, which has a flared inlet requiring a degree of elasticity in the annulus. We assigned valves to either an intra-annular or supra-annular position, but the precise position may be intermediate to these depending on suture technique, and a valve may even on occasion be placed diagonally in the annulus.

Conclusion

There are wide differences between nominal size and actual size. There is an even wider range of nominal sizes that can fit into a standard tissue annulus, as modeled by a machined cylinder. This means that hemodynamic comparisons cannot reliably be made between historical studies by assuming that nominal sizes are similar. A clearer nomenclature, which could be based on cylindric fit or an alphanumeric code, is required.

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